

### **Remarks**

Claims 1-18 and 19-36 have been canceled without prejudice or disclaimer, and new claims 37-57 have been added. Applicants hereby reserve the right to pursue canceled subject matter in subsequently filed continuing applications.

New claims 37-57 have been added in order to claim additional embodiments of the subject matter of the provisionally-elected group. Support for these claims can be found throughout the specification as filed. In particular, support for new claims 37-41 can be found, for example, in the specification at page 10, paragraph 6; at page 75, paragraph 278; at page 77, paragraph 287; and at Figures 3 and 4. Support for new claims 47-52 can be found, for example, in the specification at page 11, paragraph 7, at page 12, paragraph 15, and at page 14, paragraph 24. Support for new claims 42-44 and 53-55 can be found, for example, in the specification at page 13, paragraph 19 to page 14, paragraph 22. Support for new claims 45 and 56 can be found, for example, in the specification at page 15, paragraph 31. Support for new claims 46 and 57 can be found, for example, in the specification at pages 15-16, paragraph 32. Accordingly, no new matter has been added and entry of the present amendment and remarks are respectfully solicited.

Original claim 19 and new claims 37-57 are pending.

#### **I. The Restriction Requirement**

Pursuant to the Office Action mailed April 28, 2004, the Examiner has required an election under 35 U.S.C. §§ 121 and 372 of one of Groups I-XII. The Examiner contends that the inventions or groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding technical feature under PCT Rule 13.2.

Preliminarily, Applicants note that the Examiner has not taken the preliminary amendment of the claims filed with the instant application into account when preparing the restriction requirement, although the amendment was clearly processed by the Office. *See* Official Filing Receipt indicating 21 total claims, not 36. In particular, claims 2, 4, 6, 8-10, and 23-31 were canceled, and thus should not have been included in the restricted groups. The claims were also substantially amended, such that the sequences included in the groups by the Examiner do not agree with the claims placed into those groups. Moreover,

Applicants point out that the instant application is not a national stage filing of an International Application under 35 U.S.C. § 371, but is a divisional of such a filing, and thus restriction under 35 U.S.C. § 372, PCT Rules 13.1 to 13.2, and M.P.E.P. § 1850 is improper. For a proper restriction of the instant application, the restriction practice under 37 C.F.R. §§ 1.142(b) and 1.145 and M.P.E.P. § 821.03 should be followed. However, Applicants nevertheless respond to the restriction requirement herein; should the Examiner reissue the restriction requirement or redraft the groups in the next action, Applicants will conform the election and pending claims accordingly.

Applicants provisionally elect, *with traverse*, the invention of Group III represented by new claims 37-57, drawn to ADAM polypeptides corresponding to SEQ ID NO:15, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. Applicants point out that claims 1-18 and 19-36 have been canceled without prejudice or disclaimer, and that new claims 37-57 are directed to subject matter falling within the ambit of Group III as cast by the Examiner.

With respect to the Examiner's division of the invention into twelve groups, and the reasons stated therefore, Applicants respectfully disagree and traverse. Although the Examiner has stated that the inventions have "directed to a product of unrelated structure and function" (page 3, paragraph 4), Applicants respectfully disagree. Applicants note that the inventions of Groups I-XII are indeed related and exhibit substantial similarity as disclosed in the specification, for example, at pages 2-9, paragraph 5. Thus, a search of the claims of any of the groups would also provide useful information for the claims of the other groups. Moreover, even assuming, *arguendo*, that Groups I-XII are each directed to distinct and independent inventions, restriction remains improper unless it can be shown that the search and examination of all groups would entail a "serious burden." M.P.E.P. § 803. Applicants nonetheless submit that a search of the claims of any of the groups would also provide useful information for the claims of the other groups. For example, in many if not most publications disclosing a protein, the authors also disclose nucleic acids encoding the protein, and antibodies to the protein. Thus, since the searches for proteins, nucleic acids encoding such proteins, and antibodies to such proteins commonly overlap, the combined search and examination of such compositions would not entail a serious

burden. Accordingly, in view of M.P.E.P. § 803, the claims of all of Groups I-XII should be searched and examined together in the present application.

Further, even if the Examiner's restriction of the instant invention under 35 U.S.C. § 372 were proper, Applicants respectfully disagree with the Examiner's reasons for restriction. In particular, Applicants assert that many of the groups are also linked so as to form a single general inventive concept under PCT Rule 13.1, and thus should be examined together. Applicants note that SEQ ID NO:2 is described in the specification, for example, at page 75, paragraph 277, as the amino acid sequence of the disintegration region of SEQ ID NO:1 and SEQ ID NO:15. Thus, at the very least, the polypeptides of Group I and III share the sequence of the polypeptide of Group II, thereby forming a single general inventive concept, e.g., the amino acid sequence of SEQ ID NO:2. Moreover, MPEP Appendix AI (the PCT Administrative Instructions) explicitly recognizes that unity of invention exists between a protein and the DNA sequence encoding that protein:

**Example 17**

Claim 1: Protein X

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

MPEP Appendix AI, at AI-60 (emphasis added). See also MPEP § 1850 at 1800-61 (accepting the examples in Annex B of the Administrative Instructions as examples of unity of invention). Accordingly, in view of MPEP § 1850, MPEP Appendix AI, PCT Article 27(1), and PCT Rule 13.1, Applicants submit that the instant restriction requirement does not comply with PCT Rule 13.1 regarding unity of invention.

For the reasons set forth above, the restriction of Groups I-XII is improper under 35 U.S.C. § 121 and under 35 U.S.C. § 372. Applicants therefore respectfully request that the restriction requirement under 35 U.S.C. §§ 121 and 372 be reconsidered and rewritten, or withdrawn.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

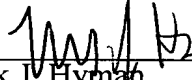
### **Conclusion**

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for examination, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: May 26, 2004

Respectfully submitted,

By   
Mark J. Hyman

Registration No.: 46,789  
HUMAN GENOME SCIENCES, INC.  
14200 Shady Grove Road  
Rockville, Maryland 20850  
(240) 314-1224

MJH/KC/lcc